

## PHA5239 Pharmacy Law and Ethics

**Fall 2012**

**3 Credit Hours**

### **Course Purpose:**

Legal issues are everywhere. An understanding of the American legal system gives one the tools to meaningfully participate in our society. In this course, we will discuss the contours of law, specifically focusing on the area of pharmacy law. We will examine the federal and Florida state laws that impact the practice of pharmacy, while emphasizing the legal and ethical principles applied by pharmacists in their daily decision-making. Students will learn the governmental framework within which pharmacy is practiced, as well as acquire an understanding of the laws, regulations, and the ethical responsibilities applicable to pharmacists so that they will be able to protect the public and ensure patients' wellbeing. We will also incorporate other broad areas of law into our discussions on pharmacy, such as contracts, criminal law and torts. Furthermore, students will learn legal procedure, legal terminology, and have an opportunity to reflect upon and evaluate the United States legal system, including its impact on the profession of pharmacy, through class readings, videos and discussions.

### **Course Faculty and Office Hours:**

#### ***Professor and Course Coordinator:***

W. Thomas Smith, Pharm.D., J.D.

Clinical Associate Professor

Email: [tsmith@cop.ufl.edu](mailto:tsmith@cop.ufl.edu) Office: HPNP 2333A

Phone: 352-273-5657

#### ***Distance Faculty Facilitators:***

<b>Campus</b>	<b>Professor</b>	<b>Instructor</b>
Jacksonville	Carol Motycka, Pharm.D. Assistant Dean & Campus Director  <b>Email:</b> <a href="mailto:motycka@cop.ufl.edu">motycka@cop.ufl.edu</a>	Steve Pudic, Pharm.D., J.D. <b>Email:</b> <a href="mailto:stevespudic@aol.com">stevespudic@aol.com</a>  Gary Padgett, Pharm.D., J.D. <b>Email:</b> <a href="mailto:garypadgett@bellsouth.net">garypadgett@bellsouth.net</a>
Orlando	Erin St. Onge, Pharm.D. Assistant Dean and Campus Director  <b>Email:</b> <a href="mailto:stonge@cop.ufl.edu">stonge@cop.ufl.edu</a>	Rick Allen, R.Ph., J.D.  <b>Email:</b> <a href="mailto:rallen@mateerharbert.com">rallen@mateerharbert.com</a>
St. Petersburg	Jennifer Williams, Pharm.D. Assistant Dean and Campus Director  <b>Email:</b> <a href="mailto:williams@cop.ufl.edu">williams@cop.ufl.edu</a>	

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**Graduate Teaching Assistants:**

Danijela Stojanovic, Pharm.D.,  
Ph.D. Student

**Office:** HPNP 2314

**Email:** dstojanovic@ufl.edu

Chintan Dave, Pharm.D.,  
Ph.D. Student

**Office:** HPNP 2314

**Email:** cdave@ufl.edu

Yanmin “Zoe” Zhu, BA,  
Ph.D. Student

**Office:** HPNP 2314

**Email:** zoe3695@ufl.edu

**Office Hours:**

By appointment only

**Place and Time of Class Sessions:**

- Gainesville classes and exams will be held in the HPNP Auditorium (Room # 1404).
  - Classes generally meet on Wednesdays from 10:40 am to 12:20 pm. Please note, however, that class #4 will meet on Friday 9/14 from 1:55-3:35 in room G101 (See **Appendix B** below).
- The faculty facilitators at each distance campus will schedule a day and time in which to conduct class – a time that is convenient for their particular location. However, students at all four campuses will discuss the same material each week, and exams will be conducted at each campus on the same dates and at the same times.

**How This Course Relates to the Learning Outcomes You Will Achieve in the Pharm.D. Program:**

This course prepares the Pharm.D. student to accomplish the following abilities and the related Student Learning Outcomes (SLOs) upon graduation:

- Perform pharmacist responsibilities within the medication use system and relate to the larger health care systems to assure safe and quality patient care. (SLO 3.1, 3.3)
- Communicate effectively with patients, caregivers, peer pharmacists, other pharmacy staff, and other health professionals. (SLO 4.1)
- Demonstrate ethical behaviors and adhere to legal requirements in pharmacy practice. (SLO 7.2)
- Solve complex practice problems (both patient-specific and general practice) using an evidence-based approach, other aspects of good clinical science, and informatics. (SLO8.1-8.2)

**Course Objectives:****General Objectives:**

The course will provide students with an understanding of:

- Regulations promulgated by federal agencies that directly impact the profession of pharmacy, including the federal Food and Drug Administration and the Drug Enforcement Administration.

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- Florida state law, including the statutes enacted by the Florida legislature and the detailed regulations issued by the Board of Pharmacy that govern the profession of pharmacy in the state.
  - The interrelationship of pharmacy law and ethics, including legal/ethical workplace issues such as professional negligence/malpractice, patient privacy, and conscientious objection.

***Educational Objectives:***

This course will provide students with the ability to:

- Describe what is entailed in being a responsible, virtuous and caring pharmacist.
- Understand numerous areas of American law including torts, contracts, property, and criminal law.
- Understand the American legal system, including state and federal court systems and processes, and have an awareness of current legal issues.
- Discuss federal regulation of medication development, production and marketing.
- Describe federal regulation of medication dispensing.
- Describe the closed system of controlled substance distribution.
- Explain the legal rules relating to controlled substance prescribing and dispensing.
- Evaluate the implications of federal laws for contemporary pharmacy practice.
- Describe state regulation of pharmacy practice.
- Discuss pharmacist malpractice liability.
- Discuss legal issues with ethical implications.
- Describe the normative principles in the ethical tradition of pharmacy.
- Discuss the process through which normative principles are applied to resolve ethical dilemmas in pharmacy.
- Describe the role and uses of health information technology in pharmacy systems.

***Attitudinal Objectives:***

The course will address the cognitive bases of selected attitudes and values, in order to encourage the student to develop:

- Willingness to accept responsibility for the outcomes of drug therapy.
- Respect for patients as autonomous individuals.
- Appreciation for the significant roles pharmacists play under the law in the promotion of beneficial outcomes for patients.
- Concern for the protection of legally recognized patient rights.
- Virtues essential to the ethical practice of pharmacy.

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**Ability Outcomes:**

At the end of the semester, the student will be able to:

**Thinking and Decision-Making**

- Analyze problems using legal and ethical frameworks.
- Synthesize legal and ethical principles with experiential knowledge of their practice setting to make informed, rational, and responsible decisions.

**Valuing and Ethical Decision-Making**

- Evaluate a moral dilemma and then develop a process by which to “best resolve” the dilemma.
- Synthesize knowledge of ethical theory with individual values to determine appropriate professional behavior.

**Professional Practice Management**

- Analyze federal and state pharmacy regulations to determine strategies for effective delivery of patient care.
- Synthesize legal and ethical principles within the context of pharmaceutical care to facilitate effective drug distribution and cognitive practice.

**Communication**

- Discuss legal and ethical issues and cases in class and on the course discussion board.
- Effectively explain the legal and ethical issues involved in a specific area of healthcare.

**Self-Learning**

- Exhibit intellectual curiosity; take responsibility for developing abilities and conduct continual self-assessment in order to develop an understanding of various areas of law through legal history, terminology, and cases.

***Specific Chapter Outcomes:***

Dr. Smith will provide substantive outcomes (i.e. what the student is expected to understand after reading and studying a given chapter, and watching the assigned videos) on Sakai.

**Pre-Requisite Knowledge and Skills:**

No course serves as a prerequisite for PHA5239 and no special skills are required.

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## Course Structure & Outline/Activities:

### **Course Structure:**

Multiple self-directed learning activities are required (e.g., prerecorded lecture videos for homework, readings that involve critical thinking, and discussion board participation), and each week students come to class for a face-to-face learning session (e.g., case discussion, problem set discussion); students must come to campus for exams.

### **Course Outline/Activities:**

The outline of course activities is listed at the end of this document in Appendix B. Please note that the dates/times for in-class sessions, as well as the location for such sessions are for Gainesville students only. Distance faculty will post this information for students at their respective campuses.

## Textbooks:

### **Required:**

- Aboud RR. *Pharmacy Practice and the Law*, 6<sup>th</sup> Edition. Sudbury, MA: Jones and Bartlett Publishers; 2010. (ISBN-13: 978-0-7637-8129-3).
- Veatch RM & Haddad A. *Case Studies in Pharmacy Ethics*, 2<sup>nd</sup> Edition. New York, NY: Oxford University Press; 2008. (ISBN-13: 978-0-19-530812-9).

### **Recommended:**

- Reiss BS & Hall GD. *Guide to Federal Pharmacy Law*, 7<sup>th</sup> Edition. Delmar, NY: Apothecary Press; 2010. (ISBN-13: 978-0967633268).
- Drug Enforcement Administration Office of Diversion Control. "Pharmacist's Manual: An Information Outline of the Controlled Substances Act", 2010 Edition. Available at [http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm\\_manual.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf).
- Garner BA, ed. *Black's Law Dictionary*, 3<sup>rd</sup> Pocket Edition. St. Paul, MN: West Group; 2001. (ISBN-10: 0314158626; ISBN-13: 978-0314158628).

## Active Learning Requirements:

During each live, in-class session students are required to answer poll questions (referred to as "test-your-knowledge" questions) over both state law and federal law concepts using their i-devices (e.g. iPhones, iPads, etc.). Accordingly, students must bring their i-devices to each class. Class discussions are heavily based upon students' responses to these questions. Students are also highly encouraged to participate on the weekly course discussion boards by deliberating and chatting about core concepts assigned for the given week.

## Student Evaluation & Grading:

### Evaluation Methods:

There are **250 possible points**, broken down as follows:

- Hourly Examinations (4).....**200 points total**
  - Each exam will consist of 50 questions, 1 point per question; 50 points per exam.
  - Exams 1-3 will reflect federal law and cases/concepts outlined in the reading materials, videos and class discussions.
  - Exam 4 is NOT cumulative, and will cover Florida state law concepts only.
  - Students will have **75 minutes** to complete each exam.
  - UF IDs must be blackened/bubbled in on exam scantrons.
  - **Gatorlink IDs** must be written on the top right corner of the scantron sheets.
- State Law.....**50 points total**
  - Students will select **only one** of the following options:
    - Outlines
      - 10 outlines total; each is worth 5 points.
      - See below for outline due dates.
    - Quizzes
      - 10 quizzes total; each consists of 10 multiple-choice questions, and each quiz is worth 5 points total (0.5 points/question).
      - Students will have **15 minutes** to complete each quiz on Sakai.
      - See below for quiz dates.

### Grading Scale:

92.5-100%	= A	82.5-86.4%	= B	69.5-76.4%	= C
89.5-92.4%	= A-	79.5-82.4%	= B-	64.5-69.4%	= D
86.5-89.4%	= B+	76.5-79.4%	= C+	≤64.4%	= E

- See link regarding minus grades: <http://www.isis.ufl.edu/minusgrades.html>.
- No grade of "C-" will be assigned in this course.
- See link regarding University grading policies: <https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx#averaging>.

### Class Attendance Policy:

Students will have an opportunity to be involved in this course through class discussion. It is therefore essential that students read all assigned course materials, watch and listen to all prerecorded videos, as well as attend each and every class. Attendance, however, is NOT mandatory; yet, it is highly encouraged. If you choose to come to class, it will be expected that you listen and learn. You will not be permitted to sleep, study material from another course, or play/chat on laptops, cell phones or any other electronic devices. Please note that attendance will be taken every class.

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**Students who actively participate in class by asking insightful questions and/or listening intently will be awarded 0.5 points per class** (which will be added to the student's final grade). Students who merely attend class, but fail to be attentive, will not be awarded the participation points. The awarding of such points is at the discretion of the instructor.

Generally, students must be in attendance to earn the bonus for participating; however, students excused for professional development who provide proof of event participation will be awarded the bonus at the discretion of the instructor.

## Quiz/Exam Policy:

### Quizzes:

- As mentioned above (and in the letter I sent you in June), students will select the way in which they will earn the 50 available state law points – one way is to complete 10 outlines and the other way is to complete 10 multiple-choice quizzes. Quizzes are discussed here, and outline assignments are discussed below in the section entitled “Assignment Deadlines.”
- During the 10 weeks that outlines are assigned, quizzes will be given to those students choosing the quiz option. Each quiz, taken on Sakai, consists of 10 questions over the state laws assigned to be outlined during the given week.
- Quiz questions are randomly taken from a bank of questions. Thus, no two students will take the exact same quiz.
- Each question will be worth 0.5 points; thus, each quiz will be worth 5 points (the same weight as an outline). Students will be quizzed *only* on the material assigned for that week; and quizzes are not cumulative.
- The quiz will open at 11:59 pm on the Thursday before outlines are due on Monday, and the quiz will close at 8 am on Monday (at the time outlines are due). Students will have 15 minutes to take the quiz, and the student can take the quiz during any 15 minute window between late Thursday night and early Monday morning. Once the quiz is started, however, the student will have to complete it – there will only be one opportunity (unless there is an unforeseen technical glitch, which, thankfully, happens very rarely).
- Please note that by the end of the first week of classes, students will have to decide whether to take the quizzes or complete the outlining assignments. Students will NOT be permitted to switch between options. Once a student makes a decision, it is final. There are no exceptions.
- Quiz questions will not be made available to students; however, throughout the course of the semester, about 100 questions over Florida pharmacy law will be made available for students to use to help prepare for both Exam 4 and the board exam.
- Please refer to page 8 for quiz dates and times.

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Quiz number	Date open (11:59 pm)	Date closed (8 am)	Quiz number	Date open (11:59 pm)	Date closed (8 am)
1	8/23	8/27	6	10/4	10/8
2	8/30	9/3	7	10/18	10/22
3	9/6	9/10	8	10/25	10/29
4	9/20	9/24	9	11/1	11/5
5	9/27	10/1	10	11/8	11/12

**Exams:**

The majority of student grades will be based on four hourly examinations (**September 20, October 15, November 19, & December 10**). These exams will cover the readings assigned in the text, as well as all material presented in prerecorded videos and material discussed in class (even if not found in the assigned readings). The format of the exams may be a combination of true/false and/or multiple-choice questions. All examinations will be “**closed book**” – no books, notes, outlines, electronic devices or other materials may be used during exams.

- **Please note that Dr. Smith will stop answering students’ questions about the substance of an exam at 2 pm on the Sunday before a Monday exam and at 5pm on the Wednesday before the Thursday exam.** So, students are encouraged to ask questions sooner rather than later.
- Students may NOT ask questions about the substance of the exam during the exam.
- Students will NOT have the opportunity to dispute exam questions. The statistics of each question will be reviewed, and if a particular question is outside acceptable parameters, the question will be thrown out, and every student will be deemed to have answered that question correctly.
- Discussion about the substance of an exam on the discussion boards is strictly prohibited until I send an announcement indicating that it is okay to discuss the exam. If you would like to meet with me (in-person or over the phone) to discuss the substance of completed exams, please email me so that we may schedule a time to talk.
- Exams will NOT be returned to students.

**Make-up Quiz/Exam Policy:**

**Quizzes:**

- Generally, make-up quizzes will not be offered because students have more than 3 days in which to complete the 15-minute quiz. However, Dr. Smith will entertain a student’s request to make-up a quiz and make his decisions based on the student’s special circumstances.

**Exams:**

- Students who must miss an hourly exam or the final (i.e. 4<sup>th</sup>) exam due to an **excused absence only** shall notify their instructor by voicemail or email **at least 6 hours before the exam** to ensure an opportunity to make up the missed work. Failure to do so will render the student

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unable to make up the missed exam regardless of the reason. Exceptions for extreme circumstances may be granted by an instructor.

- Excused absences include auto accident, illness (documentation required), death or illness of family members, etc.
- Students who arrive late for an exam will be given only the time remaining to take the exam. However, if a student completes his/her exam and leaves the testing room, anyone arriving after that first student departs will not be permitted to sit for the exam.
- Format of make-up exams is at the instructor's discretion; or if a make-up exam cannot be taken in a reasonable time frame (generally no later than 1 week after the regularly scheduled exam date), the grade on the 4<sup>th</sup> exam will be prorated.

### Policy on Old Quizzes and Assignments:

- Previously administered quizzes, assignments, or exams will not be made available to students to use as preparation for upcoming exams. Students will, however, have the opportunity to review the key to an exam once exam scores are released. Please watch for emails indicating when/where the exam keys will be made available.

### Assignment Deadlines:

- Students selecting this option will submit **10 outlines** over select laws throughout the semester.
- Outline assignments are **due by 8am** on 10 different Mondays throughout the semester (and, no outlines will be due the first week or during weeks where exams are scheduled in this course).
- Outlines will be turned in electronically via Sakai, and the Graduate TAs will check to see that the student turns in his/her outline on time; if the student turns the outline in on time, he/she will most likely earn full credit. TAs will also review several outline submissions from each student throughout the semester, and provide feedback. If a TA determines that the student has not performed the assignment as directed, the TA has the authority to deduct points. Rarely does this happen who take the assignments seriously (which is most everyone!).
- **No credit will be awarded for outlines received after the deadline.**
- The laws to be outlined may be found on the Florida Board of Pharmacy website [http://www.doh.state.fl.us/mqa/pharmacy/ph\\_statutes.html](http://www.doh.state.fl.us/mqa/pharmacy/ph_statutes.html). Please click on each of the 5 chapters of statutes to find the laws in those chapters issued by the Florida legislature, and then click on the rules under the "Florida Administrative Code" heading to find the laws issued by the Florida Board of Pharmacy. Please see the table below for the laws to be included in each of the 10 assignments. Outline the most recent version of the law.
- You were given a sample Missouri state outline to give you a sense of what I am looking for (posted on Sakai). There is no "best" way that I can suggest to do these assignments. I simply tell students that the outlines need to be written in such a way that you can pick them up two years from now, and understand what is written. Some students prefer to structure their outlines using bullet points, others prefer highlighting, while others like short paragraphs

written in shorthand – whatever works best for you works for me! If you feel that you want to include in your outline submissions the exact (word-for-word) language featured in these laws, this is acceptable ONLY IF you include, with EACH law, notes summarizing the takeaway point(s) of the law. This tells me that you've processed the law and have an understanding of it. We will look to see that you have interpreted the more verbose legalese into clear and concise language.

- You will earn no credit for simply cutting-and pasting the law and doing nothing else.
- As a rule of thumb, please try to keep each outline to a maximum of 10 pages. Documents of greater than 10 pages are sometimes rejected by Sakai. If your document contains more than ten pages, please email the TA assigned to you to let him/her know so that if Sakai indeed rejects your document, your TA will know to request the document from you. Note: An announcement will be sent to students alerting them of the TA assigned to them. Please keep an eye out for this announcement.
- Please see **Appendix C** for the weekly state outlining assignments.
- Please see the table below for the outline due dates.

<b>Outline number</b>	<b>Date due (by 8 am)</b>	<b>Outline number</b>	<b>Date due (by 8 am)</b>
1	8/27	6	10/8
2	9/3	7	10/22
3	9/10	8	10/29
4	9/24	9	11/5
5	10/1	10	11/12

### **General College of Pharmacy Course Policies:**

The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accommodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success

Please see the following URL for this information:

<http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

## Complaints:

Should you have any complaints with your experience in this course please visit:  
<http://www.distancelearning.ufl.edu/student-complaints> to submit a complaint.

## Appendix A: Directions for Contacting Faculty & Course Faculty List

### *Directions for Contacting Course Faculty:*

- Please post on the discussion board questions regarding the substantive material covered in this course.
- Please contact Dr. Smith and your faculty facilitator for personal matters that may affect your performance in this course.
- Please contact the TA assigned to you for questions about the outlining assignments.
- Please contact Dr. Smith for issues involving the quizzes.

## Appendix B: Schedule of Course Activities/Topics:

Week of	Class number	Gainesville Class Day/Date/Time (10:40 am – 12:20 pm)	Exam Day/Date/Time	Reading*
8/19	1	Wednesday 8/22		<ul style="list-style-type: none"> <li>• Abood pp. 1-24</li> </ul>
8/26	2	Wednesday 8/29		<ul style="list-style-type: none"> <li>• Abood pp. 39-46 (stop before “Defining &amp; Distinguishing...”)</li> <li>• Abood pp. 72-84 (stop before “Drugs Intended...”)</li> <li>• Abood pp. 117-123</li> <li>• Abood pp. 142-151(start with “[PDMA] of 1987” &amp; stop before “Drug Advertising...”)</li> </ul>
9/2	3	Wednesday 9/5		<ul style="list-style-type: none"> <li>• Abood pp. 58-72 (stop before New Drug Approval”)</li> <li>• Abood pp. 128-133 (stop before “Pharmacy Compounding...”)</li> </ul>
9/9	4	<b>Friday 9/14 in G101</b>		<ul style="list-style-type: none"> <li>• Abood pp. 46-58 (stop before “Prohibited Acts...”)</li> <li>• Abood pp. 84-100</li> </ul>
9/16	5	Wednesday 9/19	<b>Thursday 9/20 (over Classes 1-4); 7 pm – 8:15 pm</b>	<ul style="list-style-type: none"> <li>• Abood pp. 124-128 (stop before “Prescription Drug Labeling...”)</li> <li>• Veatch/Haddad pp. 52-54</li> <li>• Veatch/Haddad pp. 174-179</li> <li>• Veatch/Haddad pp. 236-254</li> </ul>
9/23	6	Wednesday 9/26		<ul style="list-style-type: none"> <li>• Abood pp. 133-142 (stop before “[PDMA] of 1987”)</li> <li>• Abood pp. 151-154</li> </ul>

9/30	7	Wednesday 10/3		<ul style="list-style-type: none"> <li>• Abood pp. 171-202</li> </ul>
10/7	8	Wednesday 10/10		<ul style="list-style-type: none"> <li>• Abood pp. 217-249</li> </ul>
10/14	9	Wednesday 10/17	<b>Monday 10/15 (over Classes 5 – 8); 7 pm – 8:15 pm</b>	<ul style="list-style-type: none"> <li>• Veatch/Haddad pp. 86-100</li> <li>• Veatch/Haddad pp. 255-266 (stop before Case 15-4)</li> <li>• Veatch/Haddad pp. 268-273</li> </ul>
10/21	10	Wednesday 10/24		<ul style="list-style-type: none"> <li>• Veatch/Haddad pp. 274-289</li> </ul>
10/28	11	Wednesday 10/31		<ul style="list-style-type: none"> <li>• Veatch/Haddad pp. 102-133</li> </ul>
11/4	12	Wednesday 11/7		<ul style="list-style-type: none"> <li>• Abood pp. 267-283 through HIPAA</li> </ul>
11/11	13	Wednesday 11/14		<ul style="list-style-type: none"> <li>• Abood pp. 370-405</li> </ul>
11/18		<b><u>No class on Wednesday 11/21!</u></b>	<b>Monday 11/19 (over Classes 9 – 13); 7 pm – 8:15 pm</b>	
11/25	14	Wednesday 11/28		<ul style="list-style-type: none"> <li>• Florida State Statutes</li> <li>• Abood pp. 329-40</li> </ul>
12/2	15	Wednesday 12/5		<ul style="list-style-type: none"> <li>• Florida State Rules</li> <li>• Abood pp. 340-53</li> </ul>
12/9			<b>Monday 12/10 (over Classes 14 – 15); 3:30 pm – 4:45 pm</b>	

\*The reading assignments above are subject to change as necessary throughout the semester.

## Appendix C: Weekly State Outline Assignments

Assignment 1 (continued on p. 13)	Assignment 2 (continued on p. 13)
<p><b>Background of Florida Pharmacy Laws and Definitions</b></p> <ul style="list-style-type: none"> <li>• 465.001 Short title</li> <li>• 465.002 Legislative findings; intent</li> <li>• 465.003 Definitions</li> </ul> <p><b>The Florida Board of Pharmacy</b></p> <ul style="list-style-type: none"> <li>• 465.004 Board of pharmacy</li> <li>• 465.005 Authority to make rules</li> <li>• 465.006 Disposition of fees; expenditures</li> <li>• 465.0155 Standards of practice</li> <li>• 465.017 Authority to inspect; disposal</li> </ul>	<p><b>Pharmacy Permits</b></p> <ul style="list-style-type: none"> <li>• 465.0156 Registration of nonresident pharmacies</li> <li>• 465.0161 Distribution of medicinal drugs without a permit</li> <li>• 465.018 Community pharmacies; permits</li> <li>• 465.0181 Community pharmacy permit required to dispense CII or CIII controlled substances</li> <li>• 465.019 Institutional pharmacies; permits</li> <li>• 465.0193 Nuclear pharmacy permits</li> <li>• 465.0196 Special pharmacy permits</li> <li>• 465.0197 Internet pharmacy permits</li> <li>• 465.022 Pharmacies; general requirements; fees</li> <li>• 465.023 Pharmacy permittee; disciplinary action</li> </ul>

Assignment 1 cont.	Assignment 2 cont.
<p><b>Pharmacist Licensure</b></p> <ul style="list-style-type: none"> <li>• 465.007 Licensure by examination</li> <li>• 465.0075 Licensure by endorsement; requirements; fee</li> <li>• 465.008 Renewal of license</li> <li>• 465.009 Continuing professional pharmaceutical education</li> <li>• 465.012 Reactivation of license; continuing education</li> <li>• 465.0125 Consultant pharmacist license; application, renewal, fees; responsibilities; rules</li> <li>• 465.0126 Nuclear pharmacist license; application, renewal, fees</li> <li>• 465.013 Registration of pharmacist interns</li> <li>• 465.014 Pharmacy technician</li> </ul> <p><b>Unlawful Acts and Consequences</b></p> <ul style="list-style-type: none"> <li>• 465.015 Violations and penalties</li> <li>• 465.016 Disciplinary actions</li> </ul>	<p><b>Pharmacy standards</b></p> <ul style="list-style-type: none"> <li>• 465.0235 Automated pharmacy systems used by long-term care facilities, hospices, or state correctional institutions</li> <li>• 465.024 Promoting sale of certain drugs prohibited</li> <li>• 465.0244 Information disclosure</li> <li>• 465.025 Substitution of drugs</li> <li>• 465.0251 Generic drugs; removal from formulary under specified circumstances</li> <li>• 465.0255 Expiration date of medicinal drugs; display; related use and storage instructions</li> <li>• 465.026 Filling of certain prescriptions</li> <li>• 465.0265 Centralized prescription filling</li> <li>• 465.0266 Common database</li> <li>• 465.027 Exceptions</li> <li>• 465.0275 Emergency prescription refill</li> <li>• 465.0276 Dispensing practitioners <b>(2012 version of the law does not include footnote 1; so, do not incl. it on your outline)</b></li> </ul>
<p><b>Assignment 3 (continued on p.14)</b></p>	<p><b>Assignment 4</b></p>
<p><b>Pharmacy standards cont.</b></p> <ul style="list-style-type: none"> <li>• 465.035 Dispensing of medicinal drugs pursuant to facsimile of prescription</li> <li>• 465.185 Rebates prohibited; penalties</li> <li>• 465.186 Pharmacist's order for medicinal drugs; dispensing procedure; development of formulary</li> <li>• 465.187 Sale of medicinal drugs</li> <li>• 465.188 Medicaid audits of pharmacies</li> <li>• 465.189 Administration of vaccines &amp; epinephrine autoinjection</li> <li>• 465.1901 Practice of orthotics and pedorthics</li> </ul> <p><b>Florida controlled substance laws</b></p> <ul style="list-style-type: none"> <li>• 893.02 Definitions (include here only those definitions not found in 465.003 – refer to Assignment 1)</li> <li>• 893.03 Standards and schedules (the info. in footnote 1 here is the same info. found in fn. 1 of 465.0276; no need to include that same information here)</li> <li>• 893.04 Pharmacist and practitioner</li> <li>• 893.055 Prescription drug monitoring program <b>(2012 version of the law does not include footnote 1; so, do not incl. it on your outline)</b></li> <li>• 893.06 Distribution of controlled substances; order forms; labeling and packaging requirements</li> <li>• 893.065 Counterfeit-resistant prescription blanks for controlled substances listed in Schedule II, Schedule III, or Schedule IV</li> <li>• 893.07 Records</li> </ul>	<p><b>General requirements applicable to drugs and health care</b></p> <ul style="list-style-type: none"> <li>• 456.0392 Prescription labeling</li> <li>• 456.0575 Duty to notify patients</li> <li>• 456.0635 Medicaid fraud; disqualification for license, certificate, or registration</li> <li>• 456.41 Complementary or alternative health care treatments</li> <li>• 456.42 Written prescriptions for medicinal drugs</li> <li>• 456.43 Electronic prescribing for medicinal drugs</li> <li>• 252.358 Emergency-preparedness prescription medication refills</li> </ul> <p><b>Florida Drug and Cosmetic Act</b></p> <ul style="list-style-type: none"> <li>• 499.006 Adulterated drug or device</li> <li>• 499.007 Misbranded drug or device</li> <li>• 499.0121 Storage and handling of prescription drugs; recordkeeping</li> <li>• 499.01211 Drug wholesale distributor advisory council</li> <li>• 499.01212 Pedigree paper</li> <li>• 499.028 Drug samples or complimentary drugs; starter packs; permits to distribute</li> <li>• 499.029 Cancer drug donation program</li> <li>• 499.032 Phenylalanine; prescription required</li> <li>• 499.033 Ephedrine; prescription required</li> </ul>

<p style="text-align: center;"><b>Assignment 3 cont.</b></p> <ul style="list-style-type: none"> <li>• 893.08 Exceptions</li> <li>• 893.11 Suspension, revocation, and reinstatement of business and professional licenses.</li> <li>• 893.1495 Retail sale of ephedrine and related compounds</li> </ul>	
<p style="text-align: center;"><b>Assignment 5</b></p> <p><b>Organization &amp; Purpose</b></p> <ul style="list-style-type: none"> <li>• 64B16-25.170 Probable cause panel</li> </ul> <p><b>Licensure Issues</b></p> <ul style="list-style-type: none"> <li>• 64B16-26.1001 Examination and application fees</li> <li>• 64B16-26.1002 Initial license fees</li> <li>• 64B16-26.1003 Active license renewal fees</li> <li>• 64B16-26.1004 Inactive license election; renewal; fees</li> <li>• 64B16-26.1005 Retired license election; renewal; fees</li> <li>• 64B16-26.1012 Approved continuing education provider renewal fee</li> <li>• 64B16-26.1021 Delinquent license reversion; reinstatement; fees</li> <li>• 64B16-26.1022 Permit fees</li> <li>• 64B16-26.103 Continuing education credits</li> <li>• 64B16-26.1031 Influenza immunization certification program and application</li> <li>• 64B16-26.1032 Influenza immunization administration certification application</li> <li>• 64B16-26.104 Exemptions for members of the armed forces; spouses</li> <li>• 64B16-26.200 Examination requirements</li> <li>• 64B16-26.203 Licensure by examination; application</li> <li>• 64B16-26.2031 Licensure by examination; foreign pharmacy graduates</li> <li>• 64B16-26.2032 Pharmacy intern registration internship requirements (US pharmacy students/graduates)</li> <li>• 64B16-26.2033 Pharmacy intern registration internship requirements (Foreign pharmacy students/graduates)</li> <li>• 64B16-26.204 Licensure by endorsement</li> <li>• 64B16-26.300 Consultant pharmacist licensure</li> <li>• 64B16-26.301 Subject matter for consultant pharmacist training program</li> <li>• 64B16-26.302 Subject matter for consultant pharmacist licensure renewal continuing education</li> </ul> <p>***NOTE: I will not quiz/test you on fee amounts.</p>	<p style="text-align: center;"><b>Assignment 6</b></p> <p><b>Licensure Issues cont.</b></p> <ul style="list-style-type: none"> <li>• 64B16-26.303 Nuclear pharmacist licensure</li> <li>• 64B16-26.304 Subject matter for nuclear pharmacist license renewal continuing education programs</li> <li>• 64B16-26.320 Subject matter for continuing education to order and evaluate laboratory tests</li> <li>• 64B16-26.350 Requirements for pharmacy technician registration</li> <li>• 64B16-26.351 Standards for approval of registered pharmacy technician training programs</li> <li>• 64B16-26.355 Subject matter for registered pharmacy technician continuing education</li> <li>• 64B16-26.400 Pharmacy interns; registration; employment</li> <li>• 64B16-26.600 Tripartite continuing education committee</li> <li>• 64B16-26.601 Standards for approval of courses and providers</li> <li>• 64B16-26.6012 Guidelines for board ordered disciplinary continuing education courses</li> <li>• 64B16-26.603 Continuing education records requirements</li> </ul> <p><b>Pharmacy practice standards</b></p> <ul style="list-style-type: none"> <li>• 64B16-27.100 Display of current license; pharmacist, registered pharmacy technician intern identification</li> <li>• 64B16-27.1001 Practice of pharmacy</li> <li>• 64B16-27.1003 Transmission of prescription orders</li> <li>• 64B16-27.101 Counterfeit drugs</li> <li>• 64B16-27.103 Oral prescription and copies</li> <li>• 64B16-27.104 Conduct governing pharmacists and pharmacy permittees</li> <li>• 64B16-27.1042 Rebates prohibited; violations defined</li> <li>• 64B16-27.105 Transfer of prescriptions</li> <li>• 64B16-27.120 Ordering and evaluation of laboratory tests</li> <li>• 64B16-27.200 Purpose and effect</li> </ul>

<b>Assignment 7</b>	<b>Assignment 8</b>
<p><b>Pharmacy practice standards cont.</b></p> <ul style="list-style-type: none"> <li>• 64B16-27.210 General terms and conditions to be followed by a pharmacist when ordering and dispensing approved medicinal drug products</li> <li>• 64B16-27.211 Prescription refills</li> <li>• 64B16-27.220 Medicinal drugs which may be ordered by pharmacists</li> <li>• 64B16-27.230 Fluoride containing products</li> <li>• 64B16-27.300 Standards of practice – continuous quality improvement program</li> <li>• 64B16-27.410 Registered pharmacy technician to pharmacist</li> <li>• 64B16-27.420 Registered pharmacy technician responsibilities</li> <li>• 64B16-27.430 Responsibilities of the pharmacist</li> <li>• 64B16-27.440 Policies and procedures</li> <li>• 64B16-27.500 Negative drug formulary</li> <li>• 64B16-27.510 Identification of manufacturer</li> <li>• 64B16-27.520 Positive drug formulary</li> <li>• 64B16-27.530 Duty of pharmacist to inform regarding drug substitution</li> <li>• 64B16-27.615 Possession and disposition of sample medicinal drugs</li> <li>• 64B16-27.700 Definition of compounding</li> <li>• 64B16-27.797 Standards of practice for compounding sterile preparations (CSPs)</li> <li>• 64B16-27.800 Requirement for patient records</li> <li>• 64B16-27.810 Prospective drug use review</li> </ul>	<p><b>Pharmacy practice standards cont.</b></p> <ul style="list-style-type: none"> <li>• 64B16-27.820 Patient counseling</li> <li>• 64B16-27.830 Standards of practice – drug therapy management</li> <li>• 64B16-27.831 Standards of practice for the dispensing of controlled substances for treatment of pain</li> <li>• 64B16-27.850 Standards of practice for orthotics &amp; pedorthics</li> <li>• 64B16-27.851 Record-keeping for orthotics and pedorthics</li> </ul> <p><b>Standards for pharmacy permits</b></p> <ul style="list-style-type: none"> <li>• 64B16-28.101 Prescription area accessible to inspection</li> <li>• 64B16-28.102 Sink and running water, sufficient space, refrigeration, sanitation, equipment</li> <li>• 64B16-28.1035 Patient consultation area</li> <li>• 64B16-28.108 All permits – labels and labeling of medicinal drugs</li> <li>• 64B16-28.1081 Regulation of daily operating hours</li> <li>• 64B16-28.109 Prescription department; padlock; sign: “prescription department closed”</li> <li>• 64B16-28.110 Outdated pharmaceuticals</li> <li>• 64B16-28.113 Permits; single entity; single location</li> <li>• 64B16-28.118 Unit dose and customized patient medication package returns by in-patients</li> <li>• 64B16-28.1191 Unclaimed prescriptions</li> <li>• 64B16-28.120 All permits – storage of legend drugs; prepackaging</li> <li>• 64B16-28.140 Record maintenance systems for community, special-limited community, special-closed systems, special parenteral/enteral, and nuclear permits</li> <li>• 64B16-28.141 Requirements for an automated pharmacy system in a community pharmacy</li> </ul>
<p><b>Assignment 9 (continued on p.16)</b></p>	<p><b>Assignment 10 (continued on p.16)</b></p>
<p><b>Standards for pharmacy permits cont.</b></p> <ul style="list-style-type: none"> <li>• 64B16-28.202 Closing of a pharmacy; transfer of prescription files</li> <li>• 64B16-28.2021 Change of ownership</li> <li>• 64B16-28.203 Transfer of medicinal drugs; change of ownership; closing of a pharmacy</li> <li>• 64B16-28.301 Destruction of controlled substances – institutional pharmacies</li> <li>• 64B16-28.303 Destruction of controlled substances all permittees (excluding nursing homes)</li> <li>• 64B16-28.450 Centralized prescription filling, delivering and returning</li> <li>• 64B16-28.451 Pharmacy common database</li> <li>• 64B16-28.501 Institutional permit – consultant pharmacist of record</li> </ul>	<p><b>Standards for pharmacy permits cont.</b></p> <ul style="list-style-type: none"> <li>• 64B16-28.606 Remote medication order processing for Class II institutional pharmacies</li> <li>• 64B16-28.607 Automated pharmacy system – long term care, hospice, and prison</li> <li>• 64B16-28.702 Modified Class II institutional pharmacies</li> <li>• 64B16-28.800 Special pharmacies</li> <li>• 64B16-28.810 Special pharmacy – limited community permit</li> <li>• 64B16-28.820 Sterile products and special parenteral/enteral compounding</li> <li>• 64B16-28.830 Special – closed system pharmacy</li> <li>• 64B16-28.840 Special – nonresident (mail service)</li> <li>• 64B16-28.850 Special pharmacy – ESRD</li> <li>• 64B16-28.860 Special pharmacy – parenteral/enteral extended scope permit</li> </ul>

<b>Assignment 9 cont.</b>	<b>Assignment 10 cont.</b>
<ul style="list-style-type: none"> <li>• 64B16-28.502 institutional permit and Class II institutional permit – labels and labeling of medicinal drugs for inpatients of a nursing home</li> <li>• 64B16-28.503 Transmission of starter dose prescriptions for patients in Class I institutional or modified II B facilities</li> <li>• 64B16-28.602 Class II Institutional dispensing</li> <li>• 64B16-28.6021 Class II institutional pharmacy – emergency department dispensing</li> <li>• 64B16-28.603 Class II Institutional pharmacy operating hours</li> <li>• 64B16-28.604 Class II Institutional pharmacy department security</li> <li>• 64B16-28.605 Class II Institutional pharmacies – automated distribution and packaging</li> </ul>	<ul style="list-style-type: none"> <li>• 64B16-28.870 Special-ALF</li> <li>• 64B16-28.900 Definitions – nuclear pharmacy</li> <li>• 64B16-28.901 Nuclear pharmacy – general requirements</li> <li>• 64B16-28.902 Nuclear pharmacy – minimum requirements</li> </ul> <p><b>Prescriber rules related to pharmacy practice</b></p> <ul style="list-style-type: none"> <li>• 64B8-9.012 Standards for the prescription of obesity drugs</li> <li>• 64B8-9.014 Standards for telemedicine prescribing practice</li> </ul>

\*\*\*If you choose to submit an outline, please simply submit your first outline on Sakai by 8 am Monday (8/27). Please be sure to submit your outline according to the group you've been assigned (see spreadsheet under 'Resources' tab for group assignments).

If you choose the quiz option, please simply take the first quiz (which opens on 8/23 at 11:59 pm, & closes at 8am Monday the 27th).

Either submitting your first outline or taking (or simply even attempting) your first quiz alerts Dr. Smith to the choice that you've made. Once your choice is made, it is final!